

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A microparticle less than about 20 microns in diameter, comprising:
a polymeric matrix;
a lipid; and
a nucleic acid molecule, wherein the nucleic acid molecule is contained within the microparticle, and wherein the microparticle ~~does not comprise~~ is not encapsulated in a liposome and the microparticle does not comprise a cell.
2. (Original) The microparticle of claim 1, wherein the nucleic acid molecule is circular.
3. (Original) The microparticle of claim 1, wherein the nucleic acid is a plasmid.
4. (Original) The microparticle of claim 1, wherein the nucleic acid molecule comprises an expression control sequence operatively linked to a coding sequence.
5. (Original) The microparticle of claim 1, further comprising a targeting molecule.
6. (Original) The microparticle of claim 1, further comprising a stabilizer.
7. (Original) A preparation of microparticles comprising a plurality of the microparticles of claim 1.

8. (Currently Amended) A microparticle less than about 20 microns in diameter, comprising:

a polymeric matrix;

a lipid; and

a nucleic acid molecule comprising an expression control sequence operatively linked to a coding sequence, wherein the coding sequence encodes an expression product comprising an amino acid sequence selected from the group consisting of:

(a) a polypeptide at least 7 amino acids in length, having a sequence identical to the sequence of (i) a fragment of a naturally-occurring mammalian protein; (ii) a fragment of a naturally-occurring protein from an infectious agent which infects a mammal; (iii) a plurality of the fragments of (i), linked in tandem; or (iv) a plurality of the fragments of (ii), linked in tandem;

(b) a peptide having a length and sequence which permit it to bind to an MHC class I or II molecule;

(c) a polypeptide comprising ~~consisting of~~ at least two peptides of (b) either linked in tandem or sharing generated from an overlapping sequence; and

(d) any of (a), (b), or (c) linked to a trafficking sequence,

provided that the expression product optionally includes an amino terminal methionine residue, and further provided that the expression product does not have an amino acid sequence identical to that of a full-length, naturally-occurring protein,

wherein the nucleic acid molecule is contained within the microparticle, and wherein the microparticle ~~does not comprise~~ is not encapsulated in a liposome and the microparticle does not comprise a cell.

9. (Original) The microparticle of claim 8, wherein the lipid is selected from the group consisting of a cationic lipid, an anionic lipid, and a zwitterionic lipid.

10. (Original) The microparticle of claim 8, wherein the lipid is cetyltrimethylammonium.

11. (Original) The microparticle of claim 8, wherein the lipid is a phospholipid.

12. (Original) The microparticle of claim 8, wherein the lipid is phosphatidylcholine.

13. (Original) The microparticle of claim 8, further comprising a second lipid.

14. (Original) The microparticle of claim 8, wherein the expression product is a polypeptide consisting of at least two peptides of (b) linked in tandem, wherein the at least two peptides of (b) are not identical.

15. (Currently Amended) The microparticle of claim 8, wherein the expression product is a polypeptide comprising ~~consisting of~~ at least two overlapping peptides of (b).

16. (Original) The microparticle of claim 8, wherein the expression product comprises a peptide having a length and sequence which permit it to bind an MHC class I molecule.

17. (Withdrawn) The microparticle of claim 8, wherein the expression product comprises a peptide having a length and sequence which permit it to bind an MHC class II molecule.

18. (Original) The microparticle of claim 8, wherein the expression product is immunogenic.

19. (Original) The microparticle of claim 14, wherein the expression product is immunogenic.

20. (Original) The microparticle of claim 15, wherein the expression product is immunogenic.

21. (Original) The microparticle of claim 16, wherein the expression product is immunogenic.

22. (Withdrawn) The microparticle of claim 17, wherein the expression product is immunogenic.

23. (Cancelled)

24. (Withdrawn) The microparticle of claim 8, wherein the expression product consists of an amino acid sequence identical to the sequence of a fragment at least 10 amino acids in length of a protein selected from the group consisting of myelin basic protein (MBP), proteolipid protein (PLP), invariant chain, GAD65, islet cell antigen, desmoglein, α -crystallin, and β -crystallin, wherein the fragment binds to an MHC class II molecule.

25. (Withdrawn) The microparticle of claim 8, wherein the expression product comprises an amino acid sequence identical to a sequence selected from the group consisting of SEQ ID NOS 1-46.

26. (Original) The microparticle of claim 8, wherein the expression product comprises a trafficking sequence selected from the group consisting of a sequence which trafficks to endoplasmic reticulum, a sequence which trafficks to a lysosome, a sequence which trafficks to an endosome, a sequence which trafficks to an intracellular vesicle, and a sequence which trafficks to the nucleus.

27. (Withdrawn) The microparticle of claim 8, wherein the expression product comprises an amino acid sequence identical to the sequence of an antigenic portion of a tumor antigen.

28. (Withdrawn) The microparticle of claim 8, wherein the tumor antigen is selected from the group consisting of the proteins listed in Table 3.

29. (Withdrawn) The microparticle of claim 8, wherein the expression product comprises an amino acid sequence identical to the sequence of an antigenic fragment of a protein naturally expressed by an infectious agent selected from the group consisting of a virus, a bacterium, and a parasitic eukaryote.

30. (Withdrawn) The microparticle of claim 29, wherein the infectious agent is selected from the group consisting of herpes simplex virus, hepatitis B virus, hepatitis C virus, *Plasmodium* species, *Chlamydia*, and mycobacteria.

31. (Withdrawn) The microparticle of claim 29, wherein the infectious agent is human papilloma virus.

32. (Withdrawn) The microparticle of claim 29, wherein the infectious agent is human immunodeficiency virus.

33. (Original) A preparation of microparticles comprising the microparticle of claim 8.

34. (Previously Presented) A method of eliciting an immune response against an antigen in a mammal, comprising administering to the mammal an amount of the microparticle of claim 8 effective to elicit an immune response against the expression product.

35. (Previously Presented) The method of claim 34, wherein the microparticle is introduced into a mucosal tissue of the mammal.

36. (Original) The method of claim 35, wherein the mucosal tissue is vaginal tissue.

37-50. (Cancelled)

51. (Previously Presented) A method of introducing a nucleic acid to a target site in a mammal, comprising administering an effective amount of the preparation of claim 7 directly at a target site in a mammal.

52. (Currently Amended) A preparation comprising a plurality of microparticles, each of which comprises a polymeric matrix, a nucleic acid molecule, and a lipid, wherein the nucleic acid molecule is contained within the microparticle, and wherein the microparticles do not comprise are not encapsulated in liposomes and the microparticles do not comprise a cells.

53. (Previously Presented) The preparation of claim 52, wherein the lipid is selected from the group consisting of a cationic lipid, an anionic lipid, and a zwitterionic lipid.

54. (Previously Presented) The preparation of claim 53, wherein the lipid is a cationic lipid.

55. (Previously Presented) The preparation of claim 54, wherein the lipid is cetyltrimethylammonium.

56. (Previously Presented) The preparation of claim 52, wherein the lipid is a phospholipid.

57. (Previously Presented) The preparation of claim 56, wherein the lipid is phosphatidylcholine.

58. (Currently Amended) The preparation of claim 52, ~~further comprising~~ wherein each of the microparticles comprises a second lipid.

59. (Previously Presented) The preparation of claim 52, wherein the microparticles further comprise a stabilizer compound.

60. (Previously Presented) The preparation of claim 52, wherein the microparticles further comprise a carbohydrate.

61. (Previously Presented) The preparation of claim 59, wherein the microparticles further comprise a carbohydrate.

62. (Previously Presented) The preparation of claim 52, wherein the nucleic acid molecule is a plasmid.

63. (Previously Presented) The preparation of claim 52, wherein at least 50% of the nucleic acid molecules in the microparticles are supercoiled.

64. (Previously Presented) The preparation of claim 61, wherein at least 90% of the microparticles have a diameter less than about 11 microns.

65. (Previously Presented) The preparation of claim 52, wherein the polymeric matrix is biodegradable.

66. (Previously Presented) The preparation of claim 52, wherein the polymeric matrix comprises a synthetic, biodegradable copolymer.

67. (Previously Presented) The preparation of claim 66, wherein the copolymer is polylactic-co-glycolic acid (PLGA).

68. (Previously Presented) The preparation of claim 67, wherein the ratio of lactic acid to glycolic acid in the copolymer is within the range of about 1:2 to about 4:1 by weight.

69. (Previously Presented) The preparation of claim 67, wherein the ratio of lactic acid to glycolic acid in the copolymer is about 65:35 by weight.

70. (Previously Presented) The preparation of claim 52, wherein the microparticles are suspended in a pharmaceutically acceptable carrier.

71. (Previously Presented) The preparation of claim 52, wherein the nucleic acid molecule comprises an expression control sequence operatively linked to a coding sequence.

72. (Currently Amended) A preparation comprising a plurality of microparticles, each of which comprises:

a polymeric matrix;

a lipid;

a proteinaceous antigenic determinant; and

an isolated nucleic acid molecule which encodes an antigenic polypeptide,

wherein the nucleic acid molecule is contained within the microparticle, and wherein the microparticles do not comprise are not encapsulated in liposomes and the microparticles do not comprise a cells.

73. (Previously Presented) The preparation of claim 72, wherein the isolated nucleic acid molecule is a plasmid.

74. (Previously Presented) The microparticle of claim 1, wherein the nucleic acid molecule is an oligonucleotide.

75. (Previously Presented) The preparation of claim 52, wherein the nucleic acid molecule is an oligonucleotide.

76. (Previously Presented) The method of claim 51, wherein the nucleic acid is an oligonucleotide.

77. (Previously Presented) The microparticle of claim 1, wherein the lipid is phosphatidylethanolamine.

78. (Previously Presented) The microparticle of claim 8, wherein the lipid is phosphatidylethanolamine.

79. (Previously Presented) The preparation of claim 52, wherein the lipid is phosphatidylethanolamine.

80. (Previously Presented) The preparation of claim 72, wherein the lipid is phosphatidylethanolamine.